DESCRIPITION/SPECIFICATION/STATEMENT OF WORK

4.1 SCOPE OF WORK:

4.1.1 The contractor shall furnish the radiopharmaceutical listed in Section 4.3 to the Department of Veteran Affairs VA Medical Center Sacramento, in accordance with the terms and conditions of this contract.

4.1.2 The Contractor shall meet all Nuclear Regulatory Commission, Department of Transportation, F.D.A., OSHA and all other applicable agency rules and regulations, both State and Federal. The Contractor is also responsible for delivering the material in accordance with the shipping protocols required by the Nuclear Regulatory Commission.

4.1.3 Contractor will adhere to USP797 regulations.

4.2 PRODUCT REQUIREMENTS:

4.2.1 The radiopharmaceutical shall be delivered as a sterile injectable unit dose of 15 mCi (range 15 – 20 mCi) calibrated for the time of day requested. The radiopharmaceutical shall be available daily, excluding Sundays.

4.2.2 The Government reserves the right to reject any radiopharmaceutical shipment that is opened and/or the Nuclear Medicine Department determines the shipment to be unacceptable and/or questionable. The Government will immediately notify the Contractor of the rejected shipment and the reason, prior to placing it in storage for decay.

4.2.3 Fludexoglucose F-18 Injection is a positron emitting radiopharmaceutical containing no-carrier added radioactive 2-deosy-2-F18 Fluro-D-glucose, which is used for diagnostic purposes in conjunction with Positron Emission Tomography (PET). It is administered by intravenous injection. The Fludeoxygluscose F-18 injection is a radiolabeled analog of glucose that is rapidly distributed to all organs of the body after intravenous administration. After background clearance of FDG injection, optimal PET/CT imaging is 60 minute after administration.

4.2.3.1 The active ingredient 2-deoxy-2-[18F] fluro-D-glucose (Fludeoxyglucose G-18), abbreviated 18-FDG, has a molecular formula of C6H11 18FO5 with a molecular weight of 181.26 daltons. 18-FDG injection is provided as a ready to use isotonic, sterile, pyrogen free, clear, colorless citrate buffered solution. Each mL contains between .37 to 3.7 GBq (10 – 100mCi) of 2-deoxy-2-[18]fluro-D-glucose at the end of synthesis(EOS), 4.5 mg of sodium chloride and 7.2 mg of citrate ions. The pH of the solution is between 5.o to 7.5. The solutions packaged in multiple-dose glass vial and do not contain any preservative.

4.2.4 Physical Characteristics: Fluorine-F18 decays by positron (B +) emission and has a half-life of 109.7 minutes. The principal photons useful for diagnostic imaging are 511 keV gamma photon, resulting from the interaction of the emitted positron with an electron.

4.2.5 External Radiation: The specific gamma ray constant for fluorine F 18 is 6.0 R/hr/mCi (0.3Gy/hr/kB) at 1 cm. The half-value layer (HVL) for the 511 keV photons is 4.1 mm lead (Pb). A range of values for the attenuation of radiation results from the interposition of various thickness of Pb. The range of attenuation coefficients for this radionuclide is shown in Table 2. For example, the interposition of an 8.3 mm thickness of Pb, with a coefficient of attenuation of 0.25, will decrease the external radiation by 75%.

4.2.6 Packaging of the Product: Product shall be delivered in unit dose syringes; one per container, in D.O.T. approved radioactive material shipping containers.

4.2.7 Shelf-life of the Product: Half life is 109.7 minutes (rate of decay). Shelf-life is 10 hours.

4.2.8 Turn-around time of Product: Product will be ordered no later than 3:00 pm the day prior to the study. The dose will be shipped each morning to the department and placed in the Hot Lab until ready for use. Each dose is patient specific based on prescription. There may be an occasional need for an emergency add on doses that would need to be delivered the same day ads ordered.

4.2.9 Any dose disposed of will be decayed onsite within the Nuclear Medicine Department waste area.

4.3 ORDERING/DELIVERY REQUIREMENTS:

4.3.1 Orders shall be placed during the workday and delivery shall be required the following workday. Orders can be placed orally by telephone and/or fax transmission. Contractor shall provide one (1) delivery per day, as needed, Monday – Friday. There may be an occasional need for emergency ad- on doses that would need to be delivered the same day as ordered.

4.3.2. Delivery on request and calibrated according to the calibration time given on the order. See Schedule below for quantities. The Government will order the quantities required according to the schedule need and usage of each shipment. Since this product does not have a shelf- life, no shipments will be made by the Contractor without a call from the Nuclear Medicine Department.

Anticipated Supplies required based on 12 months usage:

F-18 FluoroDeoxyGlucose – 720 doses
F-18 Naf Sodium Fluoride – 20 doses
Rb-82 Rubidium with generator – 3

4.3.3 Delivery Commitment: Time of delivery specified or mutually agreed to at the time of receipt of telephone order shall become mandatory upon the Contractor. All deliveries shall be shipped according to the manufacturer's instructions. All deliveries shall be controlled and monitored by the contractor to ensure that each delivery is received by the required due date and time.

4.3.4 Delivery Location: Deliveries will be made to:

VA Medical Center Sacramento
ATTN: Nuclear Medicine Department (115), Bldg 650
10535 Hospital Way
Mather, CA 95655

4.3.4.1 Deliveries made during off hours need to contact VA Police, in Main Lobby, to obtain access to Hot Lab. All deliveries are to be signed in, log in sheets kept in the Hot Lab.

4.3.5 Point Of Contact: The Contracting Officer will delegate a Contracting Officer's Technical Representative(S) (COTR) to monitor the Contractor's performance. The delegation will specify the limits of the COTR's authority. The COTR for this contract is Ms. Janet H. Silvestri, Chief Nuclear Medicine Technologist, telephone number 916-843-9213.